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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,627	12/10/2001	Emil Wei-Ming Fu	4-31692A	4092

1095            7590            09/10/2004  
**NOVARTIS**  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER
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VENCI, DAVID J

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/016,627	FU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David J Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 03/19/02.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-49 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-49 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities:

On page 7, the paragraph beginning "Figure 2.", the sentence beginning "A 2-Da mass shift between (A) and (B)... is indefinite because it is unclear how a mass shift is indicative of differential protein expression when the specification has not yet defined "differentially expressed."

On page 7, the paragraph beginning "Figure 3.", the sentence beginning "A 4-Da mass shift between (A) and (B)... is indefinite because it is unclear how a mass shift is indicative of differential protein expression when the specification has not yet defined "differentially expressed."

The apparent interchangeable usage of the terms "inverse" (see e.g. p. 15, second paragraph, "the inverse should be observed..."), "reversal" (see e.g. p. 11, first paragraph, "an isotope peak intensity ratio reversal..."), "converse" (see e.g. p. 11, second paragraph, "two converse collaborative labeling experiments...") and "inverted" (see e.g. p. 19, "When the labeling is inverted...") is indefinite. Applicants are required to provide definitions for each of these terms, or provide correlation to art-recognized definitions.

Appropriate correction is required.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful

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process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-49 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-49 of copending Application No. 10/412,964. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Allowable Subject Matter***

Claims 1-49 are allowable.

The following is a statement of reasons for the indication of allowable subject matter:

Applicants' claimed invention embodies, *inter alia*, a method for the spectrometric determination of differentially expressed proteins. Both the instant invention and the prior art teach a mass spectrometric method for the determination of differentially expressed proteins using isotopically labeled internal standards. For example, the prior art teaches a method comprising two protein mixtures — an experimental mixture and a reference mixture — where one or both of the mixtures are isotopically labeled. After labeling, the two mixtures are combined and analyzed by mass spectrometry. Intra-spectra analysis of labeling patterns

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is used to identify and quantify proteins in the experimental mixture (see e.g. Gygi et al. 17 NAT. BIOTECHNOL. 994 (1999).

The prior art does not appear to teach or suggest the specific step of providing four protein mixtures: an isotopically heavy-labeled reference pool, an isotopically heavy-labeled experimental pool, an isotopically light-labeled reference pool, and an isotopically light-labeled experimental pool (see claims 1(b), 23(b), 35(c), 47(a)). The prior art does not appear to teach or suggest the specific steps of combining the isotopically light-labeled reference pool with the isotopically heavy-labeled experimental pool (see claims 1(c), 23(c), 35(d), 47(b)), and combining the isotopically heavy-labeled reference pool with the isotopically light-labeled experimental pool (see claims 1(d), 23(d), 35(e), 47(c)). Finally, the prior art does not appear to teach or suggest the step of inter-spectra analysis or comparison of labeling patterns of the aforementioned combined pools to identify differentially expressed proteins (see claims 1(f), 23(f), 35(g), 47(e)).

Therefore, Applicants' method for identifying differentially expressed proteins appears to be free of the prior art.

***Conclusion***

Claims 1-49 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci  
Examiner  
Art Unit 1641

djv

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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6/07/04